UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,465	12/09/2003	Jeffrey A. Whitsett	10872/0507287	5274

26874 7590 03/28/2006

FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

EXAMINER	
MONTANARI, DAVID A	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,465	WHITSETT ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/09/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-75 are examined in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23 and 31-38, drawn to a transgenic non-human mammal, wherein the mammal carries a targeted disruption in the coding sequence of an endogenous surfactant protein C (SP-C) gene and wherein the targeted disruption inhibits production of wild-type surfactant protein C so that the phenotype of the mammal is characterized by a pulmonary disorder condition consistent with changes in humans with familial SP-C deficiency, classified in class 800, subclass 8.

II. Claims 24-30, drawn to a method of testing an agent for effectiveness against a pulmonary condition using a transgenic mouse that is homozygous for an surfactant protein C null allele, classified in class 800, subclass 3.

III. Claims 40-41, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is an antibody, classified in class 530, subclass 388.2.

IV. Claims 40 and 42, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a protein, classified in class 514, subclass 2.

V. Claims 40 and 43-46, 48-50, 52, and 54-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such

treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via retrovirus, classified in class 514, subclass 44.

VI. Claims 40 and 43-45, 47-51, and 54-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via a liposome, classified in class 514, subclass 44.

VII. Claims 40 and 43-45, 47-50, 52-62, drawn to a method of treating pulmonary disease in a subject comprising the administration to a subject in need of such treatment a therapeutically effective amount of a formulation comprising a SP-C therapeutic wherein said therapeutic is a nucleic acid and is delivered via adenovirus, classified in class 514, subclass 44.

VIII. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs of a mammal a SP-C therapeutic agent, wherein said agent is an antibody, classified in class 530, subclass 388.2.

IX. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs

of a mammal a SP-C therapeutic agent, wherein said agent is a protein, classified in class 514, subclass 2.

X. Claim 63, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response in a mammal, comprising administering to the lungs of a mammal a SP-C therapeutic agent, wherein said agent is a nucleic acid, classified in class 514, subclass 44.

XI. Claims 64-66, 72, and74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is an antibody, classified in class 530, subclass 388.2.

XII. Claims 64-67 and 74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a protein, classified in class 514, subclass 2.

XIII. Claims 64-66, 68-69 and 74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent,

wherein said agent is a nucleic acid and is delivered with a liposome, classified in class 514, subclass 44.

XIV. Claims 64-66, 68, 70-71 and 74-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a nucleic acid and is delivered with a adenovirus, classified in class 514, subclass 44.

XV. Claims 64 and 73-75, drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease involving inflammation, comprising an anti-inflammatory agent effective for reducing eosinophilic inflammation and a SP-C therapeutic agent, wherein said agent is a nucleic acid and a protein, classified in class 514, subclass 44.

Groups I and II are distinct. Group I is a transgenic non-human mammal. Group II is a method of testing an agent using a transgenic mouse that is homozygous for a null protein C allele. The transgenic non-human mammal of group I can be used for separate uses from the method of testing in a transgenic mouse in group II.

Groups III-VII are distinct from each other. Each of groups III-VIII are drawn to a method of treating pulmonary disease in a subject, however each method would require separate and different protocols to facilitate the method of treating a pulmonary disease.

The delivery of an antibody, protein, and nucleic acid via retrovirus, adenovirus, or liposome are each distinct methods of treatment and thus would require materially distinct protocols to practice the claimed methods.

Groups VIII-X are distinct. Each of group VIII-X are drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease. However each method prescribes a different type of SP-C therapeutic agent, either antibody, protein, or nucleic acid. Each of the methods for prescribing treatment would require materially separate and distinct protocols to practice each method.

Groups XI-XV are distinct. Each of groups XI-XV are drawn to a formulation for protecting a mammal from airway hyperresponsiveness, airflow limitation and/or airway fibrosis associated with a respiratory disease. Each formulation of groups XI-XV would require materially distinct and separate protocols to create said formulations.

Groups I-II are distinct from groups III-XV. The transgenic non-human mammal, and method of testing an agent in a transgenic mouse of groups I-II are of separate uses and would require materially distinct and separate protocols from groups III-XV.

Groups III-VII are distinct from groups I-II and VIII-XV. The method of treatment of groups III-VII is separate from and requires materially distinct protocols from groups I-II and VIII-XV.

Groups VIII-X are distinct from groups I-VII and XI-XV. The method for prescribing treatment is of a separate use from groups I-VII and XI-XV, and would further require materially distinct protocols from said groups.

Groups XI-XV are distinct from groups I-X. The formulation of groups XI-XV are of separate uses from group I-X, and thus would require materially distinct protocols.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required is different among each group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, Ph.D